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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------|------------------|
| 10/754,115   | 01/07/2004  | Timothy D. Hey       | DAS-104XC1                  | 8974             |
| 23557  | 7590        | 12/21/2005           |                             |                  |
| SALIWANCHIK LLOYD & SALIWANCHIK<br>A PROFESSIONAL ASSOCIATION<br>PO BOX 142950<br>GAINESVILLE, FL 32614-2950 |             |                      | EXAMINER<br>KOSSON, ROSANNE |                  |
|  |             |                      | ART UNIT                    | PAPER NUMBER     |
|  |             |                      | 1653                        |                  |

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/754,115

Applicant(s)

HEY ET AL.

Examiner

Rosanne Kosson

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15 and 18-20 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, drawn to a method of controlling insects via Protein A, Protein B and Protein C, classified in class 514, subclass 2.
- III. Claims 18-20, drawn to a method of controlling insects via a first Protein A, a second Protein A, Protein B and Protein C, classified in class 514, subclass 2.

Although Applicants' response to the Restriction Requirement Office action of September 14, 2005 has been received, electing Group I, SEQ ID NO: 34 (Protein A), SEQ ID NO: 45 (Protein B) and SEQ ID NO: 47 (Protein C), it has been determined that claims 1-15 recite a different invention than claims 18-20, and further restriction is required.

The inventions are distinct, each from the other because of the following reason.

Group I and Group III recite two different methods. In Group I, only one insecticide is required for contacting an insect, Protein A, while in Group III, two different insecticides are required for contacting an insect, a first and a second Protein A. Inventions III and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the

subcombination as claimed because the second Protein A has stand-alone insecticidal activity. The subcombination has separate utility such as controlling or inhibiting insects by exposing them to the toxic effects of the first Protein A, which has stand-alone insecticidal activity. Therefore, Inventions I and III are patentably distinct.

If Group III is elected, Applicants must also elect one sequence for the second Protein A for examination: either SEQ ID NO: 21 or SEQ ID NO: 59. This is not a species election, but an election of a patentably distinct invention because each of these sequences has a different structure and is chemically and functionally distinct. Moreover, each sequence requires a separate search. Applicants should note that searching each polypeptide sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for one discrete amino acid sequence, and each result set from a particular database must be carefully considered. Each set of prior art has its own considerations with respect to anticipation and obviousness. Hence, the search for even two different polypeptides in the databases, in addition to searching the organic molecule databases, would require extensive searching and review. Therefore, these inventions are patentably distinct.

Applicants should note that SEQ ID NO: 21 is a nucleic acid sequence. If this TcdA protein is represented by a different SEQ ID NO:, Applicants are requested to provide that information. In their response to a previous restriction requirement Office action, Applicants have stated that certain SEQ ID NOs representing nucleic acid

sequences represent both the nucleic acid sequences and the protein sequences as combined sequences. In reply, when a Sequence Listing is prepared with PatentIn software, where a coding region of a DNA sequence is designated, the software automatically generates the corresponding protein sequence and aligns it with the DNA sequence. The SEQ ID NO: represents only the DNA sequence. As discussed previously, Applicants may wish to check their SEQ ID NOs to insure that appropriate amino acid sequences are being claimed, and searched upon examination. The sequence listing is 276 pages long, and it would be best if Applicants corrected any sequence mishaps prior to examination.

Additionally, the search for any one group differs from the search for any other group, thereby creating an undue burden of search and examination. Burden lies not only in the search of U.S. patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning written description, enablement and clear and definite claim language. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is clearly proper.

**Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

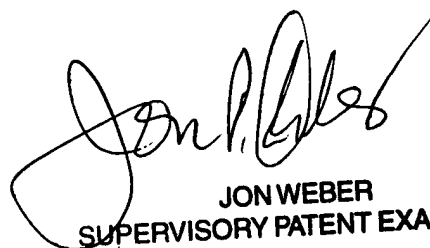
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson  
Examiner, Art Unit 1653

rk/2005-12-14



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**